

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent Application of Wei SUN, <i>et al.</i>	: Group Art Unit: 1649 : :
Appln. No:	10/540,968	: Examiner: Hugh M. Jones : :
Filed:	September 26, 2005	: : Attorney Docket No.: : 046528-5047 (415078)
For:	METHODS AND APPARATUS FOR COMPUTER-AIDED TISSUE ENGINEERING FOR MODELING, DESIGN AND FREEFORM FABRICATION OF TISSUE SCAFFOLDS, CONSTRUCTS, AND DEVICES	: : : : : : :

Declaration of WEI SUN, Ph.D., Under 37 C.F.R. § 1.131

1. I, Wei Sun, am a named co-inventor of the present application, U.S. App. Ser. No. 10/540,968.
2. I am a Professor of Mechanical Engineering and Biomedical Engineering at Drexel University.
3. The present application, U.S. App. Ser. No. 10/540,968, is a national stage entry application of PCT/US04/15316, filed May 14, 2004, which claims priority to U.S. Provisional App. No. 60/520,272, filed November 14, 2003.
4. This Declaration is offered as proof to establish that the subject matter of the presently claimed invention was invented and reduced to practice by me prior to February 22, 2003.
5. Attached hereto as Exhibit A is an unpublished, draft manuscript which I created prior to February 22, 2003.

6. Attached hereto as Exhibit B are unpublished depictions of the claimed apparatus which I created prior to February 22, 2003.

7. I invented and reduced to practice the claimed apparatus, as well as the claimed processes the apparatus performs, prior to February 22, 2003, as evidenced by the subject matter described and illustrated in both the unpublished, draft manuscript I created and the depictions of the apparatus I created prior to February 22, 2003.

8. The unpublished manuscript of Exhibit A describes the process for construction of heterogeneous CAD modeling based composite unit cells. As explained in the unpublished manuscript of Exhibit A, the constructed unit cell is a multi-volume based CAD model with material heterogeneity assigned as a design attribute in the volume. Modified Boolean operation with reasoning merging and extracting is developed to execute the object manipulation between different materials (volumes). The heterogeneous unit cell model is capable of capturing the designed geometrical configuration and reinforcement orientation at the individual constituent phases, as well as retaining the distinctive reinforcement and matrix material properties. In addition, the developed unit cell model is also intended for implementation with available CAD/CAE/CAM systems for integrated design, simulation, and manufacturing of advanced composites.

9. The unpublished depictions of Exhibit B illustrate various designs of a multi-nozzle biopolymer deposition apparatus for implementing the processes described in the unpublished manuscript of Exhibit A. The depicted apparatus of Exhibit B is a multi-nozzle printer designed to process the desired scaffold model and convert it into a layered process tool path, as well as to simultaneously deposit materials to construct the scaffold.

10. It is my understanding that the pending claims (claims 1-10) of the present application read on the subject matter and apparatus as depicted in Exhibits A and B, as well as the processes the apparatus depicted in Exhibits A and B performs.

11. It is my understanding that the earliest date for which U.S. Pat. No. 7,051,654 (hereinafter '654) can be considered as a prior art reference is May 30, 2003.

12. Regardless of what the '654 patent allegedly discloses, I invented and reduced to practice the claimed features of the presently claimed apparatus and processes performed by the apparatus prior to February 22, 2003, as evidenced by attached Exhibits A and B. It is my understanding that the earliest filing date available for the '654 patent to qualify as a prior art reference occurs after February 22, 2003. Therefore, I invented and reduced to practice the claimed features of the presently claimed apparatus prior to whatever is disclosed and described in the '654 patent.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

November 10, 2010

(date)



Wei Sun, Ph.D.

EXHIBIT A

Modeling and Layered Manufacturing Fabrication of Heterogeneous Objects

Abstract

The advancements in design and manufacturing, integrated CAD/CAE/CAM (Computer-Aided Design /Computer-Aided Engineering/Computer-Aided Manufacturing) and rapid prototyping technology have brought dramatic changes in today's industry^[1-4]. The major thrust in supporting this technological evolution is the utilization of CAD modeling, particularly the use of solid modeling. Solid modeling, which evolved as the powerful standard modeling technique in advanced CAD system (Figure 1), is used as the central repository in design communication, simulation, and manufacturing in a concurrent engineering environment.

However, these technological advancements seem to produce little impact on the design and manufacturing of advanced composites. Among many factors, this may be contributed by the inherent complexities of geometrical configuration and manufacturing of composite structures, and most importantly, by lacking of a capable CAD modeling which can simultaneously characterize composite structural complexity, material heterogeneity, and manufacturing processing. Commonly available solid modelers, regardless of B-rep, CSG, or hybrid B-rep and CSG based modeling architectures, contain geometry and topological information. They are generally limited only to construct mono-material homogeneous object. For example, B-rep modeler stores the actual design model and information only for topological and geometric relation between vertices, edges and faces, and CSG modeler stores the instructions for how to construct the geometric design model from Boolean operation to the selected primitives^[5], neither of them has addressed the materials being used in the object construction.

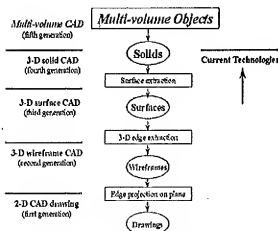


Figure 1: Evolution of CAD Modeling

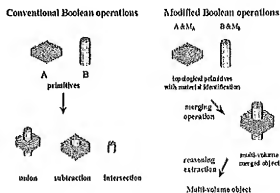


Figure 2: Reasoning Boolean Operation

This paper will present an approach to construct heterogeneous CAD modeling based composite unit cells. The constructed unit cell is a multi-volume based CAD model with material heterogeneity assigned as design attribute in the volume. Modified Boolean operation with reasoning merging and extracting is developed to execute the object manipulation between

different materials (volumes). The heterogeneous unit cell model is capable of capturing the designed geometrical configuration and reinforcement orientation at the individual constituent phases, as well as retaining the distinctive reinforcement and matrix material properties. In addition, the developed unit cell model is also intended to implement with available CAD/CAE/CAM systems for integrated design, simulation, and manufacturing of advanced composites.

Topic presented in this paper is highlighted as following:

Principle of heterogeneous CAD modelling

Research on multi-materials and multi-attributes CAD modeling has become only of recent vintage. See, for example, Masuda^[6] proposed a topological operators and Boolean operations for complex-based non-mainfold geometric models. Laakko and Mantyla^[7] suggested a s-sets finite aggregates approach by using simplex sets solids combining with conventional Boolean operation. Rossignac and Requicha^[8] developed a constructive non-regularized geometry method which could store mixed geometric objects. Cavalcanti, Carvalho and Martha^[9] used an approach for spatial decomposition of heterogeneous objects. Sun and Lau^[10] proposed a knowledge-enriched CAD modeling for solid freeform realization of heterogeneous material structure.

This paper proposes a new heterogeneous CAD modeling approach to construct the composite object by multi-volume topological elements (solids) manipulated by modified Boolean operation (Figure 2). The appropriate material identification are assigned as design attributes to the topological volumes in order to account for the material heterogeneity. A reasoning merging and extracting operation algorithm is developed and added to the conventional Boolean operator for the purpose of constructing multi-volume object and maintaining the surface information in the topological structure. The reasoning algorithm is performed based on the recognition and comparison of material identification assigned to volumes to judge whether the two topological elements are identical or not, and the logical reasoning is then made for appropriate execution of modified Boolean operation for merging, or generating intersecting surfaces, edges, and/or the splitting of volumes. The material identification will be consolidated for topological elements with the same material and will be retained with the splitted volumes if materials are different.

The reasoning extraction is usually follow the Boolean merging operation. For a two-volumes object, A and B with material identification M_A and M_B , the principle of the modified Boolean operation and reason algorithm is described as following:

If $M_A = M_B$, Then (single volume object with identical material identification)	
$C = A(M_A) + B(M_A)$	(conventional union)
OR $C = A(M_A) - B(M_A)$	(conventional subtract)
OR $C = A(M_A) \cap B(M_A)$	(conventional intersect)
Otherwise (multi-volume object with different material identification)	
$C = A(M_A) - B(M_B)$	$(M_A \text{ dominant subtract})$
or $C = B(M_B) - A(M_A)$	$(M_B \text{ dominant subtract})$
OR $C = A(M_A) + \{B(M_B) - A(M_A)\}$	$(M_A \text{ dominant union})$
or $C = B(M_B) + \{A(M_A) - B(M_B)\}$	$(M_B \text{ dominant union})$

$OR\ C = A(M_A) \cap B(M_B)$
 or $C = B(M_B) \cap A(M_A)$
 $OR\ C = \{B(M_B) - A(M_A)\} + \{A(M_A) \cap B(M_B)\}$
 or $C = \{A(M_A) - B(M_B)\} + \{B(M_B) \cap A(M_A)\}$
 end if

$(M_A\ \text{dominant}\ \text{intersect})$
 $(M_B\ \text{dominant}\ \text{intersect})$
 $(M_A\ \text{dominant}\ \text{complex_union})$
 $(M_B\ \text{dominant}\ \text{complex_union})$

In which C represents the final design object. All possible results of reasoning extraction for subtraction, union, inter-section, and complex_union for modeling two-volume object with different material identification are presented in Figure 3 and Figure 4, respectively.

Reasoning extraction for subtraction and union
- multi-volume object with different material identification

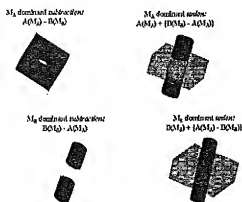


Figure 3: Reasoning extraction for subtraction and union

Reasoning extraction for intersection and complex_union
- multi-volume object with different material identification

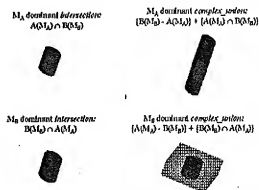


Figure 4: Reasoning extraction for intersection and complex_union

Heterogeneous CAD modeling based composite unit cells and applications

The modified Boolean operation with reasoning merging and extraction is used to construct heterogeneous CAD modeling based composite unit cells. Different from traditional composite effective element which smears reinforced constitute and matrix material for calculating composite effective properties, these unit cells can retain distinctive geometrical configurations and material properties for both constituents in composites. Following examples describe some of the unit cells constructed and applied in the modeling and simulation of heterogeneous composite structures.

a) Heterogeneous unit cells for 2D woven composites

Samples of plain woven composite unit cells

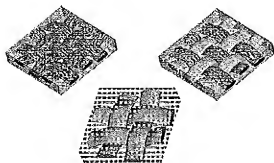


Figure 5: Unit cells for 2D woven composites

FEA Simulation of 2D Woven Unit Cell

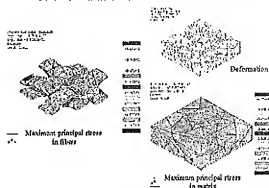


Figure 6: FEA simulation of 2D woven unit cell

b) Heterogeneous unit cells for 3D textile composites

Samples of 3D textile composite unit cells

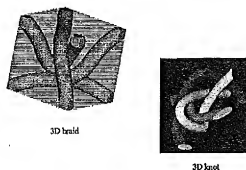


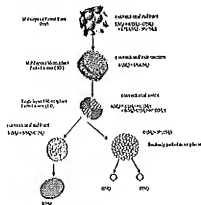
Figure 7: Unit cells for 3D textile composite

FEA Simulation of 3D Braided Unit Cell

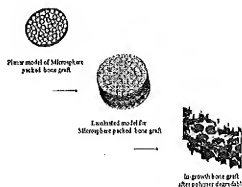


Figure 8: FEA simulation of 3D braided unit cell

c) Heterogeneous unit cells for microsphere packed tissue scaffolds



Hierarchy of structural modeling



Simulation of in-growth bone

Figure 9: Heterogeneous CAD modeling for microsphere packed tissue scaffold

d) Unit cell based design for analysis

In current research, a database of a unit cell library which contains different sets of unit cells representing different design fiber geometric and/or processing configuration of composite structure, such as various three-dimensional textile fiber configurations presented in Figure 10, will be developed. Figure 10 also describe a general concept of constructing composite structure by appropriate topological mapping of different unit cells, and application of unit cell in the finite element analysis for composite structure.

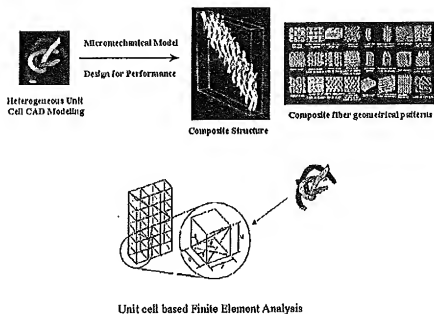


Figure 10: Unit cell based integrated design and analysis for composite structure

Design information built in the unit cell CAD model will be extracted to generate a finite element model for design simulation and analysis. As shown in previous figures, finite element meshes for both reinforcement and matrix can be generated directly from the unit cell CAD model and finite element results can be obtained at the level of constitute materials. Structural variations caused by tailored design for performance or fabrication can be adapted in design simulation by using different set of unit cells in the unit cell library. Each individual unit cell in the global composite structure illustrated in Figure 10 could be different in terms of fiber configuration or constitutive property, as long as the processing requirements are complied.

Summary

This study presents the salient features of heterogeneous CAD modeling and its application in constructing composite unit cells for design, simulation and manufacturing of advanced composites. The heterogeneity is defined as design attributes introduced in the construction of geometric and topological multi-volume object. Modified Boolean operation with reasoning merging and extraction is developed and used in the object manipulation to construct composite

unit cells. Applications of using the developed unit cells in design modeling and simulation of heterogeneous composites and tissue engineered scaffold are also presented.

This study is intended to fill the gap of using the enabling computer-aided technologies in design and manufacturing of composite materials, and fully explore the integrated CAD/CAE/CAM systems in optimal design, simulation, and manufacturing of advanced composites. The ultimate goal is to establish an integrated design for manufacturing infrastructure applied in advanced composites.

References

1. Sun, W. and Lau, A., "Design for Manufacturability and Concurrent Engineering in Integrated Product Development Process," *Proceeding of Concurrent Product Design and Environmentally Conscious Manufacturing*, Edited by S.B. Billatos and H.C. Zhang, 1997 the ASME Winter Annual Meeting, Nov. 16 - 21, 1997, Dallas, TX, pp. 113 - 124.
2. Sun, W. and Lau, A., "DFMA in Rapid Product Development," *Proceeding of The International Forum on Product Design for Manufacture and Assembly*, June 9-10, 1997, Newport, RI, pp.152-161.
3. Jo, H.H., Parsaei, H.R. and Sullivan, W.G., "Principal of Concurrent Engineering," *Concurrent Engineering - Contemporary Issues and Modern Design Tools*, Edited by Parsaei, H.R. and Sullivan, W.G., Chapman & Hall Publishing, 1993, pp. 3-23.
4. Kruth, J.P., "New Manufacturing Techniques for Rapid Prototyping and Concurrent Engineering," *Manufacturing in the Era of Concurrent Engineering*, Edited by Halevi, G. and Weill, R., North-Holland Publishing, 1992, pp. 51-82.
5. Bedworth, D.D., Henderson, M.R. and Wolfe, P.M., "Computer-Integrated Design and Manufacturing," McGraw-Hill, Inc., 1991.
6. Masuda, H., "Topological Operators and Boolean Operations for Complex-based Nonmanifold Geometric Models", *Computer-Aided Design*, Vol. 25, No. 2, 1993, pp. 119-129.
7. Laakko, T. and Mantyla, M., eiss "Feature Modeling by Incremental Feature Recognitions," *Computer-Aided Design*, Vol. 25, No. 1, 1993, pp. 479-492.
8. Rossignac, J.R. and Requicha, A.A.G., "Constructive Non-regularized Geometry," *Computer-Aided Design*, Vol. 23, No. 1, 1991, pp. 21-32.
9. Cavalcanti, P.R., Carvalho, P.C.P. and Martha, L.F., "Non-manifold Modeling: An Approach Based on Spatial Subdivision," *Computer-Aided Design*, Vol. 29, No. 3, 1997, pp. 209-220.
10. Sun, W. and Lau, A., "A Knowledge-enriched CAD Modeling and Solid Free-form Realization for Heterogeneous Material Structures", *Proceeding of The Seventh International Conference on Rapid Prototyping*, March 31 - April 3, 1997, San Francisco, CA, pp. 79 - 87.

* Correspondence author address:

Wei Sun, Ph.D.
Pei Chi Chou Assistant Professor of Mechanical Engineering
Director, Rapid Product Development Center
Department of Mechanical Engineering and Mechanics
Drexel University, Philadelphia, PA 19104, USA
Tel: (215) 895-5810, Fax: (215) 895-2094; e-mail: sunwei@drexel.edu

EXHIBIT B

